K083371

DEC - 8 2009

Attachment 3

510(k) Summary

Trade Name:	Navigator Pro, AEP Software Modification - ENoG
Common Name:	Evoked Response Somatosensory Stimulator
Classification Name:	Stimulator, auditory, evoked response -21 CFR 882.1900. This device is categorized as GWJ and is regulated as Class II.
Submitter Information:	Natus Medical Incorporated One Bio-logic Plaza Mundelein, 60060 Phone: 800-323-8326 Fax: 847-949-8615
Correspondent Information	Helen Chandler Vantage Consulting International 1011 Bugle Ct. Chapel Hill, NC 27516 Phone: 919-932-4791 Fax: 919-932-4791
Summary Prepared By:	Helen Chandler Senior Consultant
Date Prepared:	June 5, 2009
Predicate Devices:	K073626 Bio-logic Master II Evoked Response System K031009 Bio-logic Evoked Potential System K030907 Stacked ABR for Navigator Pro K070608 SmartEP K844992 Bio-logic Portable Evoked Response System

Device Description

The ENoG Protocol is a feature of the Navigator Pro with AEP Software Evoked Response System; a Windows® based software application for use with the Navigator Pro hardware platform for the recording of evoked responses (i.e., electrical potentials) upon the presentation of sensory stimuli.

The ENoG Protocol works on the basis of a repeating stimulus-response cycle. It is a convenience feature developed for the user to quickly set up testing for Electroneuronography evaluation of the facial nerves. The protocol utilizes the existing technology of the evoked response somatosensory function of the software. The evoked response from the patient is recorded through the use stimulus electrodes positioned near the mastoid, a cathode behind the earlobe, and an anode in front of the earlobe with the forehead as the ground.

Indications for Use
The ENoG Protocol is a feature of the Navigator Pro with AEP Software Evoked Response System and is intended to record evoked responses upon presentation of sensory stimuli to facial nerves. The product is indicated for use as an assessment tool to supplement the case history information, physical examination, imaging studies, and/or other sensory evaluations conducted by or on the order of the physician.

Technological Characteristics
The ENoG Protocol is a feature of the Navigator Pro with AEP Software Evoked Response System; a Windows® based software application using Evoked Response test which works on the basis of repeating a stimulus-response cycle. The evoked response is recorded through the use of two or more electrodes placed in the appropriate locations.

The technological characteristics of the ENoG Protocol feature are compared to the Bio-logic predicate devices and are summarized in the table below.

Parameter for Comparison	Similarity or Difference
Intended Use	Protocol is set-up for stimulation of facial nerves
Population	No differences
Hardware	Digitimer (K051357)
Computer Control Software	No differences
Patient Information and Tracking	No differences
Patient Connections (transducers & electrodes)	Stimulus electrodes positioned near the mastoid, a cathode behind the earlobe, and an anode in front of the earlobe with forehead as the ground. Recording electrodes are placed at the nasio-labial fold
Presentation Data/User Interface	No differences
Physical Characteristics	No differences
Safety Characteristics	No differences
Product Labeling	No differences

Safety and Effectiveness Summary
Safety and effectiveness of the ENoG protocol feature have been established throughout the design and incorporation into the Navigator Pro with AEP Evoked Response System in accordance with the Bio-logic internal product development procedures, which are intended to meet ISO-9001, ISO 13485:2003 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the Evoked Potential family of products was performed using the Fault Tree Analysis (FTA) approach, and a detailed Risk Assessment for the AEP Software was written in accordance with ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices. The ENoG protocol feature does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program "results" require a

review by a physician or other qualified healthcare professional, and may be modified, overridden or deleted as determined by a qualified user. The program provides additional functionality to allow the qualified user to review all raw data collected and perform other data analyses to suit specific requirements.

Conclusions

The indications for use are consistent with the previously indicated predicate devices and in the applicable FDA classification regulation. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness and are addressed in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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DEC - 8 2009

Re: K083371
Trade/Device Name: Navigator Pro, AEP Software Modification - ENoG
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator.
Regulatory Class: Class II
Product Code: GWF
Dated: June 4, 2009
Received: June 9, 2009

Dear Ms. Wilding:

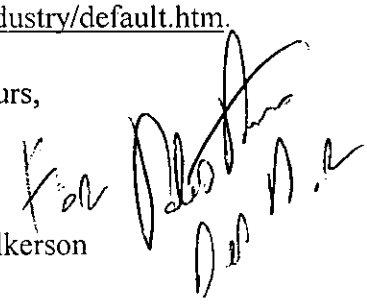
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083371

Device Name: Navigator Pro, AEP Software Modification - ENoG

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083371